

RESEARCH DURING DISASTERS

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Purpose of this talk

- Primary purpose is to discuss the ethics of research conducted during disasters.
 - Identification of:
 - a) concerns,
 - b) obstacles and
 - c) justification of getting around the obstacles.
- It should be noticed that much of this – particularly the justification of getting around obstacles -- applies equally to research in the fields of epidemiology and public health occurring apart from disasters.
 - Surveillance.
 - Outbreak investigation.
 - We can address these further during discussion.

Knowledge of disasters

- Very important but not an unconditional ethical imperative.
 - Beneficence: to enhance our power to secure human well-being [situational obligation].
- Competing ethical considerations include:
 - Respect for persons.
 - Distributive justice.
 - Non-maleficence.

Specific concerns

- Research could impede the capacity to respond to the present disaster.
- Bureaucratic requirements could delay research beyond the ‘window of opportunity’ to learn something.
 - IRB review.
 - Informed consent and its documentation.

Research impeding response to disaster

- Diversion of:
 - Energy of personnel.
 - Funds.
- Intrusive research procedures delay implementation of interventions responding immediate needs of disaster ‘victims’.
- Analogy to research in the ICU.

Research impeding response to disaster: analogical case

- Measurement of substance Q in blood during cardiac arrest:
 - Energy of personnel: 1st priority is needs of patient.
 - Nursing resource review panel.
 - Funds: A difficult problem; finite pool of funds available for research and practice.
 - Attempt to separate should be tried but ultimately fails.
- Intrusive procedures might delay implementation of interventions responding immediate needs of the patient.
 - Researchers must remain unobtrusive.

Bureaucratic obstacles

- Bureaucratic requirements could delay research beyond the ‘window of opportunity’ to learn something.
 - IRB review.
 - Multiple IRB reviews.
 - Informed consent and its documentation.
- I believe something can and must be done to alleviate each of these obstacles. The remainder of my talk will focus on the ethics of reducing these obstacles.

Distinguishing research from practice

- Groups engaged in this practice:
 - Public health practitioners including CDC.
 - Quality improvement field.
 - Historians.
 - Social and behavioral scientists
- Gerrymandering: incompatible definitions.
- Pursue exemptions instead.
 - Many public health practices use methods indistinguishable from those of research.

Exemptions: 45 CFR 46.101b(5)

- 5) Research and demonstration projects which are conducted by or **subject to the approval** of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) **possible changes in or alternatives to those programs or procedures**; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Exemptions

- Exemption from common rule coverage:
- Does **not** mean suspension of ethical standards.
- Enables **less bureaucratic oversight** procedures than common rule's specifications for IRB review.
- Enables **less formal consent** (and its documentation) than that prescribed by common rule.

Informed consent: Waivers

- Emergency exception as spelled out in FDA regulations §50.24 is:
 - Not applicable; designed for testing new therapies in situations where informed consent or permission is not feasible.
 - Entirely too bureaucratic even if applicable.

WAIVERS PERMITTED BY

SubPart A

- No more than ‘minimal risk’, and
 - Consider this definition.
- Waiver or alteration will not adversely affect the rights or welfare of subject, and
- Could not be practicably carried out without waiver, and
- ‘Whenever appropriate’, debriefing and dehoaxing.

WAIVERS PERMITTED BY

SubPart A

- (c) An IRB may ... waive the requirement to obtain informed consent ... (if):
- (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- (2) The research **could not practicably be carried out** without the waiver or alteration.

Ethics of waiver of formal informed consent requirement

- Waiver of the formal consent requirement does not show “no respect” for subject. Simple statements often suffice.
 - Survey instruments.
 - Notifications.

Closing thoughts

- I hope I have shown possibilities for removal of some bureaucratic obstacles without substantive departures from societal standards.
- Beware the impression of ‘infinite malleability’ of ethical standards.
 - Avoid revision of standards in response to perceived crisis.
 - Better to have a regular, continuing process of maintenance of sound regulations.